

In re application of
Patrick Soon-Shiong et al.
Application No.: 09/937,840
Page 2 of 15

Atty. Dkt. No. ABI1550-1 (071243-1404)

AMENDMENT OF THE CLAIMS/LISTING OF CLAIMS

Please amend claims 9, 11 and 14, and add new claims 22-47 as follows. This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Previously presented) A method for the treatment of a subject having cancer, said method comprising administering to said subject a sub-therapeutic dose level of a pharmacologically active agent effective against said cancer,

wherein said sub-therapeutic dose comprises in the range of about 1% up to about 20% of the conventionally administered amount of said pharmacologically active agent, and

wherein said sub-therapeutic dose is administered over an administration time in the range from about 7 days to about 1 year.

2. (Original) A method according to claim 1, wherein said pharmacologically active agent is selected from the group consisting of chemotherapeutic drugs, taxanes, epitholones, agents which modify microtubule activity or assembly, small molecule drugs, biologics, peptides, antibodies, enzymes, antisense therapeutics, polynucleotides, synthetic polynucleotide constructs, anti-infectives, antirejection drugs, analgesics/antipyretics, anesthetics, antiasthmatics, antibiotics, antidepressants, antidiabetics, antifungal agents, antihypertensive agents, anti-inflammatories, antineoplastics, antianxiety agents, immunosuppressive agents, antimigraine agents, sedatives/hypnotics, antianginal agents, antipsychotic agents, antimanic agents, antiarrhythmics, antiarthritic agents, antigout agents, anticoagulants, thrombolytic agents, antifibrinolytic agents, hemorheologic agents, antiplatelet agents, anticonvulsants, antiparkinson agents, antihistamines/antipruritics, agents useful for calcium regulation, antibacterial agents, antiviral agents, antimicrobials, anti-infectives, bronchodilators, hormones, hypoglycemic agents, hypolipidemic agents, proteins, nucleic acids, agents useful for erythropoiesis stimulation, antiulcer/antireflux agents, antinauseants/antiemetics, oil-soluble vitamins, mitotane, visadine, halonitrosoureas, anthrocyclines, and ellipticine.

DLMR_278354.1

In re application of
Patrick Soon-Shiong et al.
Application No.: 09/937,840
Page 3 of 15

Atty. Dkt. No. ABI1550-1 (071243-1404)

3. (Original) A method according to claim 1, wherein said pharmacologically active agent is administered by one or more routes of administration selected from the group consisting of topical, oral, intraarticular, intracisternal, intraocular, intraventricular, intrathecal, intravenous, intramuscular, intraperitoneal, intradermal/transdermal/subcutaneous, intratracheal/inhalational, rectal, vaginal, intracranial, intraurethral, intrahepatic, intraarterial, intratumoral, and mucosal.

4. (Original) A method according to claim 1, wherein said pharmacologically active agent is administered systemically.

5. (Original) A method according to claim 1, wherein said pharmacologically active agent is administered locally.

6. (Cancelled)

7. (Previously presented) A method according to claim 1, wherein said sub-therapeutic dose is administered over an administration time in the range from about 2 weeks to about 9 months.

8. (Previously presented) A method according to claim 1, wherein said sub-therapeutic dose is administered over an administration time in the range from about 3 weeks to about 3 months.

9. (Currently amended) A method according to claim 1 wherein said infirmity is breast cancer, ovarian cancer, lung cancer, hepatic disease cancer, brain disease cancer, bladder cancer or prostate cancer.

10. (Original) A method according to claim 1 wherein said subject is a human.

DLMP_278354.1

In re application of
Patrick Soon-Shiong et al.
Application No.: 09/937,840
Page 4 of 15

Atty. Dkt. No. ABI1550-1 (071243-1404)

11. (Currently amended) A method for eliminating cancer cells in a subject having said cancer cells, said method comprising administering to said subject a sub-therapeutic dose level of an antineoplastic agent,

wherein said sub-therapeutic dose comprises in the range of about 1% up to about ~~20%~~ 10% of the conventionally administered amount of said antineoplastic agent.

12. (Original) A method according to claim 11 wherein said antineoplastic agent is paclitaxel.

13. (Previously presented) A method for administration of a pharmacologically active agent to a subject in need thereof so as to achieve therapeutic levels thereof for more than 4 days, said method comprising regularly administering said pharmacologically active agent at a sub-therapeutic dose level for greater than 4 days,

wherein said sub-therapeutic dose comprises in the range of about 1% up to about 20% of the conventionally administered amount of said pharmacologically active agent.

14. (Currently amended) A method for administration of a pharmacologically active agent to a subject in need thereof without subjecting said subject to adverse events caused by higher than therapeutic levels of said pharmacologically active agent, said method comprising regularly administering said pharmacologically active agent at a sub-therapeutic dose level for a time sufficient to achieve a therapeutic effect,

wherein said sub-therapeutic dose comprises in the range of about 1% up to about ~~20%~~ 10% of the conventionally administered amount of said pharmacologically active agent.

15. (Previously presented) A unit dosage form for the treatment of a subject having cancer, said unit dosage form comprising a sub-therapeutic dose level of a pharmacologically active agent effective against said cancer,

In re application of
Patrick Soon-Shiong et al.
Application No.: 09/937,840
Page 5 of 15

Atty. Dkt. No. ABI1550-1 (071243-1404)

wherein said sub-therapeutic dose comprises in the range of about 1% up to about 20% of the conventionally administered amount of said pharmacologically active agent.

16. (Original) A unit dosage form according to claim 15, wherein the pharmacologically active agent in the unit dosage form is selected from the group consisting of chemotherapeutic drugs, taxanes, epitholones, agents which modify microtubule activity or assembly, small molecule drugs, biologics, peptides, antibodies, enzymes, antisense therapeutics, polynucleotides, synthetic polynucleotide constructs, antiinfectives, antirejection drugs, analgesics/antipyretics, anesthetics, antiasthmatics, antibiotics, antidepressants, antidiabetics, antifungal agents, antihypertensive agents, anti-inflammatories, antineoplastics, antianxiety agents, immunosuppressive agents, antimigraine agents, sedatives/hypnotics, antianginal agents, antipsychotic agents, antimanic agents, antiarrhythmics, antiarthritic agents, antigout agents, anticoagulants, thrombolytic agents, antifibrinolytic agents, hemorheologic agents, antiplatelet agents, anticonvulsants, antiparkinson agents, antihistamines/antipruritics, agents useful for calcium regulation, antibacterial agents, antiviral agents, antimicrobials, anti-infectives, bronchodilators, hormones, hypoglycemic agents, hypolipidemic agents, proteins, nucleic acids, agents useful for erythropoiesis stimulation, antiulcer/antireflux agents, antinauseants/antiemetics, oil-soluble vitamins, mitotane, visadine, halonitrosoureas, anthrocyclines, and ellipticine.

17. (Previously presented) A unit dosage form according to claim 15, wherein the pharmacologically active agent is administered by one or more routes of administration selected from the group consisting of topical, oral, intraarticular, intracisternal, intraocular, intraventricular, intrathecal, intravenous, intramuscular, intraperitoneal, intradermal/transdermal/subcutaneous, intratracheal/inhalational, rectal, vaginal, intracranial, intraurethral, intrahepatic, intraarterial, intratumoral, and mucosal.

DLMR_278354.1

In re application of
Patrick Soon-Shiong et al.
Application No.: 09/937,840
Page 6 of 15

Atty. Dkt. No. ABI1550-1 (071243-1404)

18. (Previously presented) A method according to claim 1, wherein said pharmacologically active agent is a chemotherapeutic drug.
19. (Previously presented) A method according to claim 1, wherein said pharmacologically active agent is administered intravenously.
20. (Previously presented) A unit dosage form according to claim 15, wherein the pharmacologically active agent in the unit dosage form is a chemotherapeutic drug.
21. (Previously presented) A unit dosage form according to claim 15, wherein the pharmacologically active agent is administered intravenously.
22. (New) A unit dosage form according to claim 20, wherein said chemotherapeutic drug is a taxane.
23. (New) A unit dosage form according to claim 22, wherein said taxane is paclitaxel.
24. (New) A unit dosage form according to claim 22, wherein said taxane is taxotere.
25. (New) A unit dosage form according to claim 15, wherein said sub-therapeutic dose comprises in the range of about 1% up to about 10% of the conventionally administered amount of said pharmacologically active agent.
26. (New) A method according to claim 18, wherein said chemotherapeutic drug is a taxane.
27. (New) A method according to claim 26, wherein said taxane is paclitaxel.
28. (New) A method according to claim 26, wherein said taxane is taxotere.

DLMR_278354.1

In re application of
Patrick Soon-Shiong et al.
Application No.: 09/937,840
Page 7 of 15

Atty. Dkt. No. ABI1550-1 (071243-1404)

29. (New) A method according to claim 11, wherein said pharmacologically active agent is a chemotherapeutic drug.
30. (New) A method according to claim 29, wherein said chemotherapeutic drug is a taxane.
31. (New) A method according to claim 30, wherein said taxane is paclitaxel.
32. (New) A method according to claim 30, wherein said taxane is taxotere.
33. (New) A method according to claim 13, wherein said pharmacologically active agent is a chemotherapeutic drug.
34. (New) A method according to claim 33, wherein said chemotherapeutic drug is a taxane.
35. (New) A method according to claim 34, wherein said taxane is paclitaxel.
36. (New) A method according to claim 34, wherein said taxane is taxotere.
37. (New) A method according to claim 14, wherein said pharmacologically active agent is a chemotherapeutic drug.
38. (New) A method according to claim 37, wherein said chemotherapeutic drug is a taxane.
39. (New) A method according to claim 38, wherein said taxane is paclitaxel.
40. (New) A method according to claim 38, wherein said taxane is taxotere.

DLMR_278354.1

In re application of
Patrick Soon-Shiong et al.
Application No.: 09/937,840
Page 8 of 15

Atty. Dkt. No. ABI1550-1 (071243-1404)

41. (New) A method according to claim 1, wherein said sub-therapeutic dose comprises in the range of about 1% up to about 10% of the conventionally administered amount of said pharmacologically active agent.

42. (New) A method according to claim 13, wherein said sub-therapeutic dose comprises in the range of about 1% up to about 10% of the conventionally administered amount of said pharmacologically active agent.

43. (New) A method according to claim 26, wherein said sub-therapeutic dose comprises in the range of about 1% up to about 10% of the conventionally administered amount of said taxane.

44. (New) A method according to claim 34, wherein said sub-therapeutic dose comprises in the range of about 1% up to about 10% of the conventionally administered amount of said taxane.

45. (New) A method according to claim 11, wherein said subject is a human.

46. (New) A method according to claim 13, wherein said subject is a human.

47. (New) A method according to claim 14, wherein said subject is a human.

DLMR_278354.1